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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/518,818 | 12/20/2004 | Andrew Bailey | 100730-1P US | 8247 |

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GLOBAL INTELLECTUAL PROPERTY
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WILMINGTON, DE 19850-5437

EXAMINER

LEWIS, AMY A

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| ART UNIT | PAPER NUMBER |
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1614

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| MAIL DATE | DELIVERY MODE |
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12/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,818

Applicant(s)

BAILEY ET AL.

Examiner

Amy A. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-19 is/are pending in the application.
- 4a) Of the above claim(s) 9-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/23/07.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

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DETAILED ACTION

Applicants' arguments, filed April 23, 2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-7 are examined.

Claims 9-12 remain withdrawn. Newly submitted claims 13-19 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to a compound/composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13-19 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 stand rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a method of inhibiting cathepsin S in warm blooded

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animals nor enablement for the making of the active agent of the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection is maintained for the reasons of record and further below.

Response to Applicants' Remarks:

Applicants argue that "the instant application teaches a skilled person the method of inhibiting cathepsin S in a warm blooded animals using claimed compounds without undue experimentation" (see p. 9 of Remarks). Applicants further argue that "understanding the mechanism of action is not a requirement for enablement purposes" (see p. 10, 2nd para.). Applicant also alleges that the instant applicant describes and *in vitro* assay to test the effectiveness of the compounds and using the assay to demonstrate the efficacy of the claimed compounds would not require undue experimentation (see p. 10, 3rd para.).

As stated in the previous Office Action, when there is little known in the prior art about the nature of the invention (i.e., the claimed compounds and their alleged ability to inhibit cathepsin), the specification would need more detail as to how to make and use the invention in order to be enabling. See, e.g., *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004) ("Nascent technology, however, must be enabled with a specific and useful teaching." The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction.

The Examiner acknowledges that a disclosure of *every* operable species is *not* required, in cases involving unpredictable factors, such as most chemical reactions and physiological

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activity, more may be required. Regarding Applicant's argument to the mechanism of action, Applicant is claiming just that: a mechanism of inhibiting cathepsin S in order to treat a plethora of disorders. As such, Applicant has not demonstrated any such inhibition activity or a nexus to such a mechanism having therapeutic activity. Again, the *in vivo* experiments disclosed in the specification regarding the claimed compounds and their alleged ability to inhibit cathepsin (see the assay briefly described at pp. 18-19) are prophetic and do not demonstrate enough detail to enable one skilled in the art to determine how to make and use the claimed compounds for the claimed method. Further, the breadth of the claims, especially regarding the variety in the compounds of formula (I) would likely produce great variation in response regarding the inhibition activity, thus creating an undue burden of experimentation.

Regarding the rejection of claims 1-7 for lack of enablement for the synthesis of the claimed active agents and Applicant's arguments regarding *Tetrahedron* reference, the rejection is maintained. Applicant points to Compound No. 12 on p. 3315. First, there is not compound 12 in the schematic of page 12. Further, the source compound of the *Tetrahedron* reference comprises a 5 membered ring and the instantly claimed and elected compounds have a 6 membered ring in the same position. Further, the *Tetrahedron* reference does not describe how to modify the compound with the variety of moieties instantly claimed, say for instance the cyano or sulfur containing moieties.

Therefore, in considering Applicants arguments and in light of the Wands Factors, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance

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presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue. Thus, the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

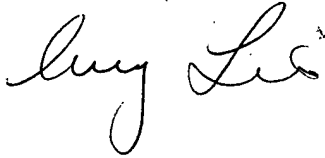
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is 571-272-9032. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy A. Lewis



ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER